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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,723	12/27/2001	Rajiv Shah	047711-0288	7474

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Irvin C. Harrington, III
FOLEY & LARDNER
35th Floor
2029 Century Park East
Los Angeles, CA 90067-3021

EXAMINER

NAFF, DAVID M

ART UNIT PAPER NUMBER

1651

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/033,723

Applicant(s)

SHAH ET AL.

Examiner

David M. Naff

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/18/05&4/19/05.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28,30 and 32-69 is/are pending in the application.
4a) Of the above claim(s) 46-66,68 and 69 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 28, 30, 32-45 and 67 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Art Unit: 1651

DETAILED ACTION

An amendment of 1/18/05 amended claims 28, 32-37 and 45-66, canceled claim 29, and added new claims 67-69.

Claims in the application are 28, 30 and 32-69.

5 A response of 4/19/05 to a restriction requirement of 3/31/05 elected Group I claims 28, 30, 32-45 and 67 with traverse.

The traverse contained no reasons in support thereof. The restriction requirement is still considered proper, and is adhered to and made final.

10 Claims 46-66, 68 and 69 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/19/05.

15 Claims examined on the merits are 28, 30, 32-45 and 67.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

20 Claims 28, 30, 32-45 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is unclear in line 3 as to whether the active protein is the active protein in solidified form of line 2. It is suggested that
25 line 3 be amended by inserting --- in solidified form --- after

Art Unit: 1651

"protein", both occurrences. With this change, line 5 should be amended before "solidified" by canceling "a" and inserting --- said --

-.

Claims 32-37 are unclear by not having clear antecedent basis in claim 28 for cross-linking the active protein. While claim 28 requires a cross-linking reagent, the claim does not require the cross-linking reagent to cross-link the active protein. Furthermore, it is unclear as to the relationship of vapor phase cross-linking in claims 32-37 to the cross-linking reagent of claim 28. Is vapor phase cross-linking in claims 32-37 using the cross-linking reagent of claim 28, or does vapor phase cross-linking involve cross-linking unrelated to the cross-linking reagent of claim 28?

Claims 32-37 are unclear how they further limit the sensor of claim 28. The claims require process conditions including a vapor phase cross-linking process of treating the active protein of claim 28. It is unclear how the process conditions of these claims change the active protein from that required in claim 28. If process limitations are required to define the sensor, the sensor should be claimed by a product-by-process claim requiring a complete process for making the sensor, and use the process limitations of claims 32-37 to further limit the process of making the sensor.

Response to Arguments

In regard to claims 32-37 requiring process conditions, applicants urge (amendment of 1/18/05) that claims 32-37 have been amended to further clarify the claims to define the type of active

Art Unit: 1651

protein used in the sensor. However, the claims still depend on process limitations to define the type of protein. It is unclear how the process limitations require a different type of active protein than required by claims that do not contain process limitations. For example, in claim 32, the active protein is exposed to a vapor phase cross-linking process. This sets forth a process condition involved in cross-linking the active protein of claim 28. It is uncertain as to characteristics of an active protein resulting from vapor phase cross-linking as in claim 32 that are different from characteristics of an active protein of claim 28 that does not require vapor phase cross-linking. These type of comments also apply to claims 33-37. Claims 32-37 should be deleted, unless it can be established that the process conditions of the claims change the active protein to have characteristics different from characteristics of the active protein of claim 28 when the process conditions are not required.

Claim Rejections - 35 USC § 102

Claims 28, 30 and 32-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Clark Jr (6,343,225).

The claims are drawn to a sensor comprising a sensor body having disposed within a space an active protein in solidified form containing glucose oxidase, human serum albumin and a cross-linking reagent, and wherein the active protein is in solidified form prior to being deposited within the space of the sensor body.

Clark Jr discloses a glucose sensor containing a cross-linked protein gel containing human serum albumin and glucose oxidase cross-

Art Unit: 1651

linked with glutaraldehyde (col 9, lines 20-41). The glutaraldehyde may be in vapor form (col 9, line 38). The gel is formed, and a small piece is placed over a platinum electrode contained by the sensor (col 9, lines 55-57 and Figure 2)

5 The sensor of Clark Jr is the same as the presently claimed sensor. The gel of Clark Jr is solidified since it is produced in the form of a self-supporting small piece, and placed over an electrode (col 9, lines 55-57). As shown by Figure 2 of Clark et al, gel 14 is placed over electrode 16 in a space formed by an outer shell 13. The
10 process conditions of dependent claims will not result in a materially different gel and biosensor than disclosed by Clark Jr.

Response to Arguments

Applicants urge that the claims have been amended to require an active protein having a solidified form prior to being disposed within
15 a space in the sensor body. However, as noted above, the gel of Clark Jr is formed before being placed over an electrode in a space formed by an outer shell.

Applicants urge that employing a gel as disclosed by Clark Jr has associated problems of difficulty of ensuring that the gel fills the
20 volume of a sensor so as not to leave voids which can adversely affect stability and sensitivity of the sensor, and the gel can shrink over time to form further voids.

This argument is unpersuasive since "solidified" as recited in the claims encompasses a gel. The gel of Clark Jr can be considered
25 solidified since it has a self-supporting structure in the form of a

Art Unit: 1651

small piece having a shape to fit next to an electrode in a space formed by an outer shell as shown by Fig. 2.

Claim Rejections - 35 USC § 103

Claims 42 and 43 are rejected under 35 U.S.C. 103(a) as being
5 unpatentable over Clark Jr.

The claims require human serum albumin to be in a concentration of approximately 23-32.5 % (w/v) of the active protein.

Clark Jr discloses human serum albumin present in an amount of 15% (col 9, line 21).

10 It would have been a matter of obvious choice depending on individual preference to use a higher amount of human serum albumin of 23-32.5% in Clark Jr in the absence of a new and unexpected result from the higher amount. An amount of 23-32.5% human serum albumin would have been expected to provide substantially the same result as
15 15%.

Response to Arguments

As set forth above, the gel of Clark Jr is a solidified form within the scope of the solidified form of the claims.

Claim Rejections - 35 USC § 103

20 Claims 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark Jr in view of Blubaugh Jr et al (5,964,993).

The claims require the active protein to further contain silicone particles.

Clark Jr is described above.

Art Unit: 1651

Blubaugh Jr et al disclose a glucose sensor containing a cross-linked protein gel containing serum albumin, Glucose oxidase and glutaraldehyde (paragraph bridging cols 7 and 8). Also disclosed is the presence of a silicon compound to facilitate the transport of oxygen to sites of glucose oxidation (col 6, lines 46-50).

It would have been obvious to include in the protein gel of Clark Jr the silicon compound taught by Blubaugh Jr et al to obtain its function to facilitate oxygen transport. Having the silicon compound in particle form as in claim 45 would have been a matter of individual preference within the skill of the art since the silicon compound would have been expected to function in particle form as when in non-particle form.

Response to Arguments

As set forth above, the gel of Clark Jr is a solidified form within the scope of the solidified form of the claims, and Blubaugh Jr is not relied on for producing the gel.

Claim Rejections - 35 USC § 103

Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clark Jr in view of Liston et al (4,891,104).

The claim requires the solidified active protein to be in the form of a pellet.

Clark Jr is described above.

Liston et al disclose an enzyme electrode containing an enzyme layer formed from a glucose oxidase/bovine serum albumin solution cross-linked with glutaraldehyde to form a bead (col 14, lines 40-46).

Art Unit: 1651

It would have been obvious to form the protein gel of Clark Jr as beads as disclosed by Liston et al to obtain the easier handling of beads. Beads can be considered to be pellets. Changing the shape of the protein gel of Clark Jr without changing its function would have
5 been well within the ordinary skill of the art.

Response to Arguments

Applicants urge that the bead of Liston et al is a liquid. However, this does not appear to be the case since the solution is cross-linked. After cross-linking, the solution will no longer be a
10 liquid. Furthermore, it does not appear a liquid would be capable of being compressed into a thin film. Such compressing would require the bead to be in a non-liquid form such as a gel. For the bead to be compressed to a film on the membrane, the bead would have to be placed on the membrane and remain in bead form before compressing. If the bead
15 is a liquid, it will not be self-supporting, and cannot be transferred to the membrane in bead form.

As set forth above, the gel of Clark Jr is a solidified form within the scope of the solidified form of the claims, and Liston et al is not relied on for producing the gel.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension
25 of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1651

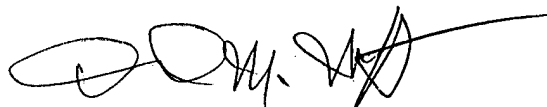
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 751-273-8300.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

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DMN
6/29/05